

AMENDED IN ASSEMBLY APRIL 2, 2013
AMENDED IN ASSEMBLY FEBRUARY 27, 2013
CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 58

Introduced by Assembly Member Wieckowski

January 7, 2013

An act to amend Section 24177.5 of the Health and Safety Code, relating to medical experiments.

LEGISLATIVE COUNSEL'S DIGEST

AB 58, as amended, Wieckowski. Medical experiments: human subjects.

Existing law regulates the conduct of medical experiments on human subjects and requires informed consent prior to conducting medical experiments on human subjects. Existing law, until January 1, 2014, exempts from this requirement a medical experimental treatment that benefits a patient subject to a life-threatening emergency if specified conditions are met, including that the patient is in a life-threatening situation necessitating urgent intervention and available treatments are unproven or unsatisfactory and informed consent cannot be obtained before treatment must be administered.

This bill would continue the exemption for life-threatening emergencies indefinitely *and would add conditions for the use of medical experimental treatment, including that the institutional review board has reviewed and approved the informed consent procedures and these procedures are to be used with subjects or their legally authorized representatives in situations where use of the procedures and documents*

is feasible and that specified additional protections of the rights and welfare of the subjects will be provided.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 24177.5 of the Health and Safety Code
2 is amended to read:

3 24177.5. (a) This chapter does not apply to a medical
4 experimental treatment that benefits a patient subject to a
5 life-threatening emergency if all of the following conditions are
6 met:

7 (1) Care is provided in accordance with the procedures and the
8 additional protections of the rights and welfare of the patient set
9 forth in Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code
10 of Federal Regulations, in effect on April 1, 2012.

11 (2) The patient is in a life-threatening emergency necessitating
12 urgent intervention and available treatments are unproven or
13 unsatisfactory.

14 (3) The patient is unable to give informed consent as a result of
15 the patient's medical condition.

16 (4) Obtaining informed consent from the patient's legally
17 authorized representatives is not feasible before the treatment must
18 be administered. The proposed investigational plan shall define
19 the length of time of the potential therapeutic window based on
20 scientific evidence, and the investigator shall commit to attempting
21 to contact a legally authorized representative for each subject
22 within that length of time and, if feasible, to asking the legally
23 authorized representative contacted for consent within that length
24 of time rather than proceeding without consent.

25 (5) There is no reasonable way to prospectively identify the
26 individuals likely to become eligible for participation in the clinical
27 investigation.

28 (6) Valid scientific studies have been conducted that support
29 the potential for the intervention to provide a direct benefit to the
30 patient. Risks associated with the investigation shall be reasonable
31 in relation to what is known about the medical condition of the
32 potential class of subjects, the risks and benefits of standard

1 therapy, if any, and what is known about the risks and benefits of
2 the proposed intervention or activity.

3 *(7) The institutional review board has reviewed and approved*
4 *the informed consent procedures and these procedures are to be*
5 *used with subjects or their legally authorized representatives in*
6 *situations where use of the procedures and documents is feasible.*

7 *(8) Additional protections of the rights and welfare of the*
8 *subjects will be provided, including, but not limited to, all of the*
9 *following:*

10 *(A) Consultation, including, where appropriate, consultation*
11 *carried out by the institutional review board, with representatives*
12 *of the communities in which the research will be conducted and*
13 *from which the subjects will be drawn.*

14 *(B) Public disclosure to the communities in which the research*
15 *will be conducted and from which the subjects will be drawn, prior*
16 *to the initiation of the research, of plans for the research and its*
17 *risks and expected benefits.*

18 *(C) Public disclosure of sufficient information following the*
19 *completion of the research to apprise the community and*
20 *researchers of the study, including demographic characteristics*
21 *of the research population and the results of the study.*

22 *(D) Establishment of an independent data monitoring committee*
23 *to exercise oversight of the research.*

24 (b) This section does not relieve any party of any other legal
25 duty, including, but not limited to, the duty to act in a nonnegligent
26 manner.